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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|---------------------|------------------|
| 10/801,062 | 03/15/2004 | Francis M. Creighton IV | 5236-000478/US | 1249 |
| 28997 | 7590 | 10/11/2006 | EXAMINER | |
| HARNESS, DICKEY, & PIERCE, P.L.C 7700 BONHOMME, STE 400 ST. LOUIS, MO 63105 | | | LAURITZEN, AMANDA L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3737 | |

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/801,062 | CREIGHTON, FRANCIS M. | |
| | Examiner | Art Unit | |
| | Amanda L. Lauritzen | 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/15/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 Mar 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/13/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed provisional application 60/454,410 filed March 13, 2003 is acknowledged under 35 U.S.C. 111(b).

Information Disclosure Statement

2. The fifth U.S. Patent Document cited in the IDS (US-2003/0113678) has not been considered because it is attributed to Creighton et al. on the form, but the inventor on the publication is K.E. Doud.

Specification

3. The specification is objected to for misspellings of the term sagittal, as in paragraph 0026, for example. Appropriate correction is required.
4. Reference characters "26" and "24" have both been used to designate the operating region of embodiment 1 when referred to in the specification. The reference 24 otherwise consistently refers to the magnet system, so the operating region cited 24 in the specification on pages 5 and 7 is regarded as typographical error and has been construed as 26 for examination purposes; however, appropriate correction is required. A number of similar errors were found in mention of other figure reference characters in the specification that also require correction.

Drawings

5. The drawings are objected to because the C-arm referenced by the characters "40" and "140" in the specification for each of two embodiments are not present in any of the figures.
6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

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sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. Claim 16 objected to because the following statement on line 4 is unclear: "...with an imaging comprising..." . Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-14 and 16-28 are rejected under 35 U.S.C. 103(a) as being obvious over Ritter et al. (U.S. Patent No. 6,241,671) in view of Creighton IV et al. (U.S. Patent No. 7,019,610).

Regarding claims 1 and 16, Ritter '671 discloses a magnetic navigation system for orienting a magnetically responsive medical device comprising a patient support and a magnet system comprising at least two magnets for applying a magnetic field of at least 0.08 Tesla in any selected direction by a change of position and/or orientation of the magnets within an exclusion zone volume (see col. 3, lines 2-9 in which a plurality of magnets provide a field of at least 0.1 T; also lines 38-39 and 49-50 in which magnets are moveable and rotatable). Further disclosed is an imaging system comprising an imaging beam source and detector disposed on opposite sides of the operating region and carried on a C-arm which can pivot about an axis generally parallel to the longitudinal axis of the subject through at least about 60° without impinging upon the exclusion zone of the magnets (col. 3, lines 58-59 and col. 4, lines 1-7 in which the C-arm support of the imaging devices can pivot freely about three axes).

Regarding the C-arm pivot angles specified in claims 2-8 and 17-23, the C-arm of the imaging system disclosed by Ritter et al. '671 freely rotates about three orthogonal axes and is therefore capable of accommodating the various angular orientations claimed with respect to both the midsagittal plane of the subject and the exclusion zone of the magnets (see the spatial arrangement of the magnet system and C-arm in Fig. 2; also col. 4, lines 1-7).

Regarding claims 13-14, 16 and 28, the imaging zone dimensions of at least ± 15 and ± 20 cm are both enabled by the invention of Ritter '671 by repositioning the C-arm to scan the desired imaging region. Additionally, the operating region of Ritter is disclosed as having a radius of at least ± 20 centimeters on either side of the centerline (col. 3, lines 14-15 in which the operating region is spherical having a radius of 12 inches, or approximately 30.5 cm).

Regarding claims 9 and 24, Ritter et al. '671 disclose that each of the at least two magnets is translatable along and rotatable about a first axis that extends radially outwardly from the center of the operating region, is pivotable about a second axis that is generally perpendicular to the first axis that extends through the center of mass of the magnet (see col. 3, lines 26-31 in which the magnets are disposed in mutually perpendicular planes; see also lines 38-39 and 49-50 in which magnets are moveable and rotatable about these orthogonal axes).

Regarding claims 12 and 27, the at least two magnets of Ritter et al. '671 are disclosed as rotatable about the operating region in fixed relation (col. 3, line 38-39).

Regarding claims 1 and 16, Ritter '671 teaches all the features of the instant invention as substantially claimed, but does not disclose the magnets of the magnet system being disposed on opposite sides of the operating region, but in the same field of endeavor Creighton et al. '610 disclose this feature. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the magnet arrangement of Creighton '610 with the invention of Ritter '671 for the purpose of projecting a magnetic field into the operating region in a patient on a patient bed as cited by Creighton et al. '610 in col. 3, lines 37-41.

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Regarding claims 10-11 and 25-26, disposing the magnets on opposite sides of the operating region as depicted in Fig. 1 of Creighton et al. '610 necessarily results in a collinear (or nearly collinear) axial arrangement of the magnets.

9. Claims 15 and 29-30 are rejected under 35 U.S.C. 103(a) as being obvious over Ritter et al. '671 in view of Creighton IV et al. '610 and Creighton et al. (U.S. Patent No. 6,630,879).

The modified invention of Ritter '671 includes all the features of the instant invention as substantially claimed but is not specific to the structure of the magnets or the exclusion zone geometry. However, in the same field of endeavor, Creighton et al. '879 disclose magnets comprised of a plurality of blocks with a magnetization direction that optimizes the magnetic field in a particular direction (col. 5, lines 32-35 in which magnets are divided into a plurality of segments). Movement of magnet 500 of Fig. 26 that is generally cylindrical with a frustoconical face inherently creates an exclusion zone in the volume of the magnet and the path it is traversed (see Creighton et al. '879 col. 15, lines 59-64 in which movement of the arcuate segment creates an associated exclusion zone volume in its path). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the magnet comprised of a plurality of blocks with an associated exclusion zone volume in order to establish the ideal local magnetization direction to properly orient the surgical instrument (see Creighton et al. '879 col. 5, lines 34-35).

10. The applied references have a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only

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under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

af

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